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Supreme Court, U.S.
FILED
MAR 12 1996
CLERK

Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

October Term, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF OF THE STATES OF FLORIDA, ARKANSAS, COLORADO, CONNECTICUT, INDIANA, KENTUCKY, MAINE, MARYLAND, MISSISSIPPI, MISSOURI, MONTANA, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OREGON, SOUTH DAKOTA, TENNESSEE, TEXAS, AND WEST VIRGINIA AS AMICI CURIAE IN SUPPORT OF LORA LOHR AND MICHAEL LOHR

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INTEREST OF THE *AMICI CURIAE*

Pursuant to Supreme Court Rule 37.5, the signatory States respectfully submit this brief as *amici curiae* in support of respondents/cross-petitioners Lora and Michael Lohr.

Amici have a strong interest in this case because they are responsible for the enforcement of laws safeguarding public health, safety, and welfare. In addition, *amici* have a strong interest in preserving the appropriate balance of authority between the States and the federal government. Through the evolution of their common law and by legislative enactments, the States have developed and refined their tort systems to balance the needs and rights of victims against the interest of manufacturers of potentially dangerous or defective products.

Pre-emption analysis asks whether congressional intent to displace state law is so clear and manifest as to give adequate notice to the States of the impending removal of their authority. This question is particularly important in cases like this one, where the asserted pre-emptive effect of the federal statute is so dramatic. *Amici* urge this Court to hold that the Medical Device Amendments of 1976 (MDA) do not displace state-law damages claims, because that act did not give the States the requisite clear notice of its sweeping pre-emptive effect.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is rooted in principles of federalism. Our federalist system requires that "consideration" of pre-emption under the Supremacy Clause "start" with the basic "presumption that Congress does *not* intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co* , 115 S. Ct. 1671, 1676 (1995) (emphasis added); *see also Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Pre-emption of state efforts to protect health and safety "should not be lightly inferred." *Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994) (internal quotation omitted). Local laws relating to health and safety are "those 'the Court

has been most reluctant to invalidate.'" *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670 (1981) (citation omitted).

Hence, state law is pre-empted only if there is "an unambiguous congressional mandate to that effect." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 147 (1963). "[P]re-emption will not lie unless it is the 'clear and manifest purpose of Congress.'" *CSX Transp., Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). "Any indulgence in construction should be in favor of the States, because Congress can speak with drastic clarity whenever it chooses to assure full federal authority, completely displacing the States." *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 780 (1947) (Frankfurter, J., dissenting).

The presumption against pre-emption is especially strong when Congress has failed to provide a separate federal remedy for a person injured by tortious conduct, because "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). The MDA does not provide a remedy for a person injured by a negligently designed or manufactured device.

The stringent showing required for pre-emption rests on fundamental "[p]rinciples of federalism." *Department of Revenue of Or. v. ACF Indus., Inc.*, 114 S. Ct. 843, 850 (1994). This Court has shown great solicitude for state sovereignty. It has ruled, for example, that the Commerce Clause is not all-encompassing, *see United States v. Lopez*, 115 S. Ct. 1624, 1631 n.3, 1632, 1634 (1995); that Congress may not "commandeer the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program," *New York v. United States*, 505 U.S. 144, 170 (1992) (citation omitted); and that, absent clear congressional intent, federal employment statutes such as the Age Discrimination in Employment Act of 1967 should not be construed as applying to state

judges and other state constitutional officers, given the importance of the "federalist structure of joint sovereigns" and the need for "a proper balance between the States and the Federal Government." *Gregory v. Ashcroft*, 501 U.S. 452, 459 (1991).

One of the vital "procedural safeguards inherent in the structure of the federal system," *see Garcia v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528, 552 (1985), is the requirement of a crystal-clear statement of congressional intent before the States are stripped of the right to govern themselves and to protect their citizens against unsafe products. "[I]nasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise. '[T]o give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Gregory*, 501 U.S. at 464 (quoting L. Tribe, American Constitutional Law § 6-25, at 480 (2d ed. 1988)); *see also U.S. Term Limits, Inc. v. Thornton*, 115 S. Ct. 1842, 1887 n.12 (1995) (Thomas, J., joined by Rehnquist, C.J., and O'Connor and Scalia, JJ., dissenting) (quoting the same sentence of American Constitutional Law and describing *Gregory* as "applying this argument").

Moreover, the overall presumption against pre-emption "provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (citation omitted). As Judge Kenneth Starr and Judge Patrick Higginbotham explained in their seminal monograph on the subject:

> When courts consider whether Congress intended to preempt state laws,...the nation's commitment to federalism would seem to argue for an *especially clear* statement of congressional intent to oust states from their

> traditional legislative functions. For if in close or uncertain cases a court proceeds to preempt state laws where that result was not clearly the product of Congress' considered judgment, the court has eroded the dual system of government that ensures our liberties, representation, diversity, and effective governance.

Judge Kenneth Starr & Judge Patrick E. Higginbotham, *et al.*, *The Law of Preemption: A Report of the Appellate Judges Conference* 47 (1991) (emphasis added).

I.

The Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 301–393, contain nothing approaching a clear statement of congressional intent to pre-empt state tort actions. The only reference to state law damages claims in the text of the MDA is a savings provision, not a pre-emption provision. This feature is not surprising in light of Congress' overall purpose in adopting the MDA: to expand consumer protection against dangerous medical devices, not to displace civil claims by victims of those devices. The MDA was an addition to the Federal Food, Drug, and Cosmetic Act of 1938, a statute that was designed to allow — and has always been construed to permit — consumers to bring state-law damages claims for injuries caused by unsafe drugs, foods, or cosmetics.

The MDA does contain a pre-emption provision, § 360k(a), but that section should be construed as addressing only state statutes, administrative regulations, and ordinances. Section 360k(a) uses the term "requirement" three times; only once, in the context of state-law requirements, is it even arguably ambiguous. In the other two references, § 360k(a) clearly uses "requirement" to mean positive enactments, not state-law claims for damages.

Moreover, § 360k(a) pre-empts only state-law requirements "with respect to a device." The text of the statute, the interpretation of the FDA, and the prior decisions of this

Court all indicate that this phrase does not include generally applicable norms of state law, such as common-law rules regarding fraud and negligence. This Court has always drawn a significant distinction between the pre-emption of specially targeted laws and pre-emption of generally applicable, background rules.

The MDA's text and structure also reinforce the conclusion that it does not pre-empt state-law damages claims. For example, the procedure by which States may petition the FDA for exemptions from pre-emption, 21 U.S.C. § 360k(b), and the reference to state-law claims for damages in the event of recalls of unsafe devices, 21 U.S.C. § 360h(d), both indicate that Congress did not intend to pre-empt state-law damage claims.

II.

Even if the MDA's pre-emptive effect extended to *some* state-law damages claims, it would not displace the claims at issue in the instant case. Like *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995), the instant case involves a product which was not approved and for which there was no governing federal safety regulation. Although *some* medical devices have entered the market pursuant to the FDA premarket approval ("PMA") process, which enables the agency to determine whether a proposed product provides "reasonable assurance of its safety and effectiveness," 21 U.S.C. § 360c(a)(C), the device at issue did *not*.

Rather, the defective pacemaker that allegedly injured Ms. Lohr entered the market as the substantial equivalent of another pacemaker that was on the market before the MDA was adopted. 21 U.S.C. § 360e(b)(1)(B). Regulatory inquiry focused not on *safety*, but on whether the defective pacemaker was *equivalent* to one already on the market. In such circumstances, the FDA has declared that its acceptance of a claim of "substantial equivalence" does "not in any way denote official approval of the device." 21 C.F.R. § 807.97.

Congress itself, in strengthening the MDA in 1990, warned that § 510(k) approval "is not equivalent to an approval by the FDA of the device's safety and effectiveness." H.R. Rep. No. 808, 101st Cong., 2d Sess. 1990, *reprinted in* 1990 U.S. Code Cong. & Admin. News 6307.

This Court should hold that, at a minimum, the § 510k process does not result in "requirements" that could pre-empt state law damages claims arising from devices that never received FDA premarket approval.

ARGUMENT

I. THE MDA DOES NOT PRE-EMPT ANY STATE-LAW CLAIMS FOR DAMAGES

"[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damages actions." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). Instead, the pre-emptive effect of federal legislation must be assessed on a statute-by-statute basis, in light of the traditional presumption against pre-emption. Thus, in *Cipollone*, this Court held that the 1965 Federal Cigarette Labeling and Advertising Act "is best read as having superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels." 505 U.S. at 518. In contrast, considering the "broad sweep" of the language in the Public Health Cigarette Smoking Act of 1969 and the legislative history of

that act, this Court found certain state-law damages claims pre-empted.[1]

A close analysis of the MDA and its legislative history indicates that it, too, was never intended to displace state-law damages claims.

A. PRE-EMPTION WOULD BE ANTITHETICAL TO THE CONGRESSIONAL PURPOSE IN ADOPTING THE MDA

The MDA is a consumer protection statute, not one that granted device manufacturers sweeping immunity from state-law claims for damages. Prior to the MDA's enactment, the FDA was not authorized to review a medical device — regardless of the dangers it posed — for safety and efficacy before it was marketed unless the agency could persuade a court to treat the device as a drug.[2] The MDA was adopted to protect consumers by giving the agency premarket regulatory author-

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1 Three Justices would have held in *Cipollone* that the 1969 Act did not pre-empt any common-law damages claims, on the ground that "[t]he effect of tort law on a manufacturer's behavior is necessarily indirect." 505 U.S. at 536 (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part and dissenting in part). Justice Blackmun also noted: "The principles of federalism and respect for state sovereignty that underlie the Court's reluctance to find pre-emption where Congress has not spoken directly to the issue apply with equal force where Congress has spoken, though ambiguously. In such cases, the question is not *whether* Congress intended to pre-empt state regulation, but to what *extent*. We do not, absent unambiguous evidence, infer a scope of pre-emption beyond that which clearly is mandated by Congress' language." *Id.* (emphasis in the original).

2 *See, e.g., United States v. An Article of Drug...Bacto-Unidisk*, 394 U.S. 784 (1969) (cardboard disk impregnated with antibiotic); *AMP, Inc. v. Gardner*, 389 F.2d 825 (2d Cir.), *cert. denied*, 393 U.S. 825 (1968) (suture product).

ity over dangerous devices.[3] Introducing the bill on the Senate floor, its sponsor, Senator Kennedy, explained that "[t]he legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S6140 (Apr. 17, 1975). The FDA has recognized that "[t]he entire thrust of the Amendments is to provide FDA with new and additional authority to assure that only safe and effective medical devices are permitted on the market." 43 Fed. Reg. 18,663 (1978).

The leading scholarly analysis on the pre-emptive effect of the MDA reports that, "except for a few passing references to the need to avoid slowing innovations in medical technology" — chiefly as a result of *federal* (not state) *overregulation*[4] — "the critical, and endlessly repeated focus of congressional attention was to protect consumers from dangerous devices." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922–23 n.126 (1994). Indeed, since medical devices were virtually *unregulated* prior to 1976, it is paradoxical to suggest that Congress adopted the MDA to "deregulate" medical devices in order to promote innovation. If Congress had wished to achieve *that* objective, it simply would have done nothing at all.

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3 H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976) ("Absent clear, statutory authority to regulate medical devices, the FDA cannot safeguard the health of the American public by assuring the safety and effectiveness of [medical devices]."); S. Rep. No. 33, 94th Cong., 2d Sess. 5 (1976) ("Although many lives have been saved or improved by [medical devices], the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the complicated technology involved in their manufacture and use.... Increasing numbers of patients have been exposed to increasingly complex devices which pose serious risks if inadequately tested or improperly designed or used.").

4 *E.g.*, H.R. Rep. No. 853 at 10 ("excessive or ill-conceived *Federal* device regulation would stifle progress in this field") (emphasis added).

The MDA manifests no intent to insulate manufacturers from damages liability under state law. There is no express reference in the statute to state-law damages claims, but only to "requirement[s]," 21 U.S.C. § 360k(a), which are best understood as state statutes, administrative rules, ordinances, and other positive enactments. *See* Part I-B, *infra*. "A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Adler & Mann, *supra*, at 923 n.128.

In constructing this regulatory framework, Congress clearly legislated against a background understanding that state tort remedies would remain available to injured consumers. The MDA is, after all, an *amendment* to the Food, Drug, and Cosmetic Act of 1938, a statute that has never been accorded broad pre-emptive effect.[5] Indeed, a proposed provision for a federal cause of action in the original Federal Food, Drug, and Cosmetic Act was deleted as being duplicative of existing state law.[6]

In the wake of the MDA's adoption, the FDA released an advisory opinion — which "represents the formal position of the FDA" and is binding on the agency, 21 C.F.R. § 10.85(e) — explaining to interested parties that the MDA did not bar

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5 *E.g.*, *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 & n.1 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988).

6 Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce, 73d Cong. 2d Sess. 400, 403 (1933).

common-law claims.[7] Similarly, in deciding whether to require medical device manufacturers to report injuries caused by their devices, the FDA assumed that product liability litigation would continue, even if device manufacturers complied with FDA requirements. *E.g.*, 45 Fed. Reg. 76183, 76188 (1980); 48 Fed. Reg. 24014, 24022 (1983); 49 Fed. Reg. 36326, 36331, 36337 (1984).[8]

After the MDA's passage courts generally allowed state-law tort claims to proceed against medical device manufacturers. For example, the Tenth Circuit affirmed a multimillion-dollar judgment in a toxic shock syndrome case, rejecting the manufacturer's claim "that its compliance with FDA standards entitled it to judgment as a matter of law." *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1443 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988). Several federal courts, as well as the Supreme Court of Kansas, held that the MDA did not bar claims arising from defective intrauterine devices (IUDs).[9] The Fifth Circuit held that state regulations regarding the fitting, sale, and packaging of hearing aids were not pre-empted.[10] And the New Jersey Supreme Court determined that state requirements regarding hearing aids were invalid only if they conflicted with specific federal regulations

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7 *See* Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to Robert E. Manchester, National Women's Health Network (Mar. 8, 1984), reprinted at Pet. App. 4a–6a in *Lohr v. Medronic, Inc.*, No. 95-886; *see also* Letter from Joseph Sheehan, Chief, Regulation Staff, Food and Drug Administration, to Cindy Whaley, Esq. (Feb. 2, 1987), reprinted at Pet. App. 7a in *Lohr v. Medronic, Inc.*, No. 95-886.

The FDA also described § 360(k)(a) as "prescrib[ing] a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law *(whether established by statute, ordinance, regulation, or court decision)*, which is different from or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act." 21 C.F.R. § 808.1(b) (emphasis added). The italicized language simply means that the pre-emptive effect of the MDA extends to court decision construing state statutes, ordinances, and regulations. *See* 43 Fed. Reg. 18,663 (1978) ("When determining whether a State or local requirement is preempted, however, the Commissioner will consider how the requirement is interpreted and applied, not merely the literal language of the applicable statute."). This meaning is especially clear in the context of the FDA's regulations addressing exemptions from pre-emption. *See* 21 C.F.R. § 808.20(c)(1) (States seeking exemptions from pre-emption must submit "a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision"; "[i]f the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations").

8 Other FDA statements shows that the agency narrowly construed the preemptive effect of § 360k(a) and limited the concept of a "requirement" to state statutes, regulations, and ordinances. *See, e.g.*, 42 Fed. Reg. 30385 (1977) ("An exemption will be granted only for those device-related requirements that have the force and effect of law, i.e., have been enacted, promulgated or issued in final form. However, an application may be submitted after the establishment of the statute or regulation by the State or local government, but before the effective date of the requirement."); 43 Fed. Reg. 18663 (1978) (state statute prohibiting sale of adulterated or misbranded devices not pre-empted because it "applies to the person who would sell the device — and thereby cause the violation — and not to the device itself").

9 *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 664 (D. Md. 1989); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1232–33 (Kan. 1987).

10 *Smith v. Pingree*, 651 F.2d 1021, 1024–25 (5th Cir. 1981).

on the topic.[11] When it amended the MDA in 1990, Congress expressed no disagreement with the narrow interpretation of the Act's pre-emptive effect that had been advanced by the FDA and many lower courts.[12] In fact, Congress explained that the purpose of the 1990 amendments was to "modify the underlying law in ways that will result in *greater* protection of the public health." H.R. Rep. No. 808, 101st Cong., 2d Sess. 13 (1990) (emphasis added).[13]

There is thus no basis for concluding that the States had any notice at all — much less "clear" notice — that the MDA would work a dramatic and unprecedented withdrawal of remedies available to injured consumers. Tellingly, not until eighteen years after the MDA's passage did courts begin to accord it broad pre-emptive effect.[14]

Nevertheless, medical device manufacturers insist that in 1976 Congress bestowed on them a blanket immunity from the state-law damages claims of the victims of defective and unsafe medical devices — even if the FDA never determined that the devices were safe. *See* Part II, *infra*. And the manufacturers' argument would apply equally to state *criminal*, as well as *civil*, liability — so that a company guilty of intentional or criminally negligent wrongdoing could not be punished under *any* form of state law.[15]

Medical devices include more than 1,700 different kinds of products, ranging from the everyday (*e.g.*, cotton swabs) to the highly complex (*e.g.*, heart pacemakers or hip replacements). It is simply inconceivable that in 1976 Congress meant to confer — or that the States would have tolerated — a blanket immunity for the manufacturers of all such products. Indeed, the MDA was prompted in large part by the emerging scandal of the "Dalkon Shield" (the A.H. Robins Company's brand name for an intrauterine birth control device or IUD), which Congress singled out as "[a]n example of a legitimate medical device which was marketed without adequate premarket testing." H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976). The Dalkon Shield was cited numerous times during the debates on the MDA in both the House and Senate.[16] A supreme irony of this case is that, if the Dalkon

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11 *New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 572 (1978); *see also Kievlan v. Dahlberg Electronics*, 144 Cal. Rptr. 585, 78 Cal. App. 3d 951 (Cal. App. 1978) (no pre-emption of California prohibition against hearing aid manufacturer representing that products have any effect on diseases or disorders of the ear).

12 This Court accords "great weight" to an amending Congress' interpretation of the underlying statute. *E.g., Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380–381 & n.8 (1969).

13 The Hawaii Supreme Court explained:

> [The legislative history of the Medical Device Amendments] reveals that Congress was concerned with *increasing* the protection afforded medical device consumers under existing law rather than with *restricting* or reforming the law in existence at the time of the Act. Moreover, in 1990, subsequent to FDA promulgation of § 808.1(d), Congress amended the Medical Device Amendments of 1976....The 1990 amendments left § 360k untouched, providing evidence that § 808.1(d) is an accurate reflection of Congressional intent under § 360k. *Larsen v. Pacesetters Systems, Inc.*, 837 P.2d 1273, 1281 (Haw. 1992) (emphasis added).

14 *See, e.g., Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

15 *Cf. United States v. C.R. Bard, Inc.*, 848 F. Supp. 287 (D. Mass. 1994) (device manufacturer pleading guilty to 391 criminal counts of violations of federal law).

16 *E.g.*, 122 Cong. Rec. H1719–1731 (daily ed. Mar. 9, 1976); 121 Cong. Rec. S6139–6162 (daily ed. Apr. 17, 1975).

Shield tragedy occurred today, Medtronic's argument would mean that the MDA would bar resultant tort claims.

In sum, as two commentators have observed, "it is inconceivable that as Draconian a measure as preempting common law tort claims founds its way into the MDA in 1976 without one word from concerned members of Congress." Adler & Mann, *supra*, at 940.

B. SECTION 360K(A) DOES NOT SUPPORT PREEMPTION OF STATE-LAW DAMAGES CLAIMS

The Court of Appeals rested its decision on § 360k(a) of the MDA, which in relevant part prohibits any State from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). If one thing is clear from this language, it is that § 360k(a) does not *expressly* say anything about state-law tort or contract claims. As numerous statutes show, Congress knows how explicitly to pre-empt such claims when it wants to do so.[17] Only one portion of the MDA's legislative history pertains to this provision, and that fragment makes clear that § 360k(a) was

17 *See, e.g.*, 21 U.S.C. §§ 1715z-17(d), 1715z-18(e) (Domestic Housing and International Recovery and Financial Stability Act); 17 U.S.C. § 301(a) (Copyright Act of 1976); 29 U.S.C. § 1144(a), (c)(1) (ERISA).

meant to address positive enactments like state statutes and regulations.[18]

Pre-emption cannot be somehow inferred from § 360k(a). That provision uses the word "requirement" three times. Only in the context of state-law "requirements" is the term even arguably ambiguous; in the other two instances, it is clear that Congress contemplated positive enactments like statutes and regulations, not common-law actions.[19]

Other features of § 360k(a) reinforce the conclusion that it has limited pre-emptive effect. The provision addresses state-

18 The House Report stated:

> The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.... In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the requirement that intrauterine devices are subject to premarket approval in California.
>
> Because there [are] some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill's general prohibition on non-Federal regulation.
>
> H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976).

19 *See* 21 U.S.C. § 360k(a)(1) (referring to "any *requirement* applicable under this Act"); *id.* at § 360k(a)(2) (referring to "a *requirement* applicable to the device under this Act").

law requirements "with respect to a device." Webster's New Collegiate Dictionary defines "respect" as "a relation to or concern with something usually specified" and defines "respecting" as "in view of" and "with regard to."[20] The common law of torts does not have any specified relationship with "a device," nor was it developed in view of or with regard to "a device." Therefore, if the phrase "with respect to a device" is to be given its plain dictionary meaning — and if this Court is to remain faithful to the tenets of federalism that underlie pre-emption doctrine — the common law and other generally applicable forms of state law do not qualify as requirements "with respect to a device." *Cf. New York Conference of Blue Cross & Blue Shield Plans*, 115 S. Ct. at 1677 ("If 'relate to' were taken to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for '[r]eally, universally, relations stop nowhere.' But that, of course, would be to read Congress's words of limitation as mere sham, and to read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality.") (citation omitted).

The decisions of this Court have often drawn a significant distinction between pre-emption of specially targeted laws and pre-emption of generally applicable, background legal norms not directed at specific conduct in particular. In *Cipollone*, for example, a plurality of this Court held that federal law would not displace liability for fraud, and conspiracy to misrepresent or conceal material facts, because such liability is predicated "on a more general obligation — the duty not to deceive." 505 U.S. at 528–29. In *New York Telephone Co. v. New York State Dept. of Labor*, 440 U.S. 519, 533 (1979), a plurality explained that congressional pre-emption of state power to "enforce...general laws is more difficult to infer than intent to pre-empt laws directed specifically at concerted activity." In *United Steelworkers of America v. Rawson*, 495 U.S.

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20 Webster's New Collegiate Dictionary 986 (1977).

362, 371 (1990), this Court distinguished, for purposes of labor-law pre-emption, between duties imposed on a labor union by a collective bargaining agreement and generally applicable obligations, such as "the duty of reasonable care owed to every person in society." And in *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992), this Court held that the federal Occupational Safety and Health Act of 1970 pre-empts only state law that "constitutes, in a direct, clear, and substantial way, regulation of worker health and safety" and does not pre-empt "state laws of general applicability (such as laws regarding traffic safety or fire safety)," despite their demonstrable effect on occupational safety. *Id.* at 107 (internal quotations omitted).

The structure of the MDA provides further indication that the statute does not pre-empt state-law damages claims. A State may petition the Secretary of Health and Human Services for an exemption from the statute's pre-emptive effects, strongly suggesting that Congress had in mind state legislation and administrative rules. 21 U.S.C. § 360k(b). As one court put it, "if the term 'requirement' were interpreted so as to include tort law, the exemption procedures would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of [a] tort plaintiff?" *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989).

Furthermore, the section of the MDA relating to recall of harmful devices provides that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law" and prescribes rules for the calculation of economic losses to plaintiffs. 21 U.S.C. § 360h(d). Hence, Congress believed that a company's compliance with an FDA recall order — a form of a federal requirement — would not bar tort claims against it. Congress would not have needed to eliminate this defense had it intended the MDA to pre-empt state tort law. This being so, the MDA hardly reflects the requisite "unambiguous con-

gressional mandate to that effect." *Florida Lime & Avocado Growers, supra*, 373 U.S. at 147.

For all these reasons, *amici* submit that the MDA does not pre-empt state-law damages claims.

II. AT A MINIMUM, THE SECTION 510K PROCESS DOES NOT PRE-EMPT CLAIMS INVOLVING MEDICAL DEVICES THAT HAVE NOT RECEIVED FDA PREMARKET APPROVAL

As noted in the opinion below, the pacemaker was two steps removed from any federal evaluation of its safety and fitness. The pacemaker was approved as a device equivalent to another pacemaker, which was already on the market and which had been grandfathered under the MDA. 56 F.3d at 1340. Even if the MDA's pre-emptive effect extended to *some* state-law damages claims, the claims before this Court would not be pre-empted. Like *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995), this case involves the principle that there can be no pre-emption in the absence of a specific federal safety requirement. *See also Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985).

The Court of Appeals correctly concluded that medical devices entering the market through the "substantial equivalence" procedure of § 510k of the Act, 21 U.S.C. § 360e(b)(1)(B), are not subject to a specific requirement for pre-emption purposes. For a device to qualify as the "substantial equivalent" of one which is already being marketed, the FDA must determine that the new device has the same intended use as the predicate device and *either* the same technological characteristics *or* the same safety and effectiveness as the predicate device. § 360c(I)(1)(A).

Therefore, the Court of Appeals correctly determined that manufacturers of such devices cannot claim the shield of the MDA to displace state tort law because "[t]he 510(k) process is focused on *equivalence*, not safety" and "510(k) approval under the MDA, standing alone, is not a finding of safety and

effectiveness and does not impose specific requirements on a device for preemption purposes." Pet. App. 27a. The FDA has declared that its acceptance of a claim of "substantial equivalence" does "not in any way denote official approval of the device." 21 C.F.R. § 807.97.

As Congress has noted, the sheer volume of devices entering the market through the § 510(k) procedure prevents the FDA from rigorously scrutinizing each device. "[O]ver 80 percent of the devices that are potentially the most dangerous (Class III) enter the market on the basis of a claim by the manufacturer that they are 'substantially equivalent' to a device already on the market." H.R. Rep. No. 808, 101st Cong., 2d Sess. 1990, *reprinted in* 1990 U.S. Code Cong. & Admin. News 6307. In strengthening the MDA in 1990, Congress documented the practical problems confronting the FDA in verifying such claims and found that "the FDA has experienced difficulties in learning about serious problems with devices." *Id.* Accordingly, Congress cautioned that 510(k) approval "is not equivalent to an approval by the FDA of the device's safety and effectiveness." *Id.*

CONCLUSION

The judgment of the Court of Appeals should be reversed in part insofar as it holds that the MDA pre-empts any state-law damages claims.

Respectfully submitted,

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